REMARKS

Applicants thank Examiner Belyavskyi for the courtesy of the interview on March 30, 2006 and for withdrawing the obviousness rejections under 35 U.S.C. § 103(a) based upon U.S. Patent No. 5,837,460 to Von Feldt *et al.* ("the '460 patent"). Claims 29-34 are presently pending and have been examined. Favorable reconsideration and allowance are respectfully requested.

The 102(e) Rejection

Claims 29-33 have been rejected under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Patent Application Publication No. US 2002/0141994 to Devalaraja et al. ("the '994 publication").

In the response dated February 10, 2006, Applicants argued that the '994 publication is only entitled to an earliest effective filing date of February 23, 2001 (for the reasons therein and as fully discussed below) and is therefore not a § 102(e) reference since that date is clearly after Applicants' earliest priority date of May 8, 2000 (for U.S. Serial No. 60/202,392).

In response to Applicants' arguments, the present Office Action states that the '994 publication was properly converted to a non-provisional application (from U.S. Serial No. 60/270,948; "Provisional B") and is therefore entitled to claim priority to provisional application filed on March 20, 2000 (U.S. Serial No. 60/190,842; "Provisional A"). No authority is cited for this conclusion. The Examiner further remarks, also without citing any authority, that this is the case because the conversion was timely made. Office Action, p.2, item 4, fourth paragraph.

However, the crux of the issue at hand is whether Provisional A was available to serve as a basis for priority which is not a matter of timing but rather a matter of entitlement. As discussed, Provisional A became abandoned on March 21, 2001 without itself being converted to

a non-provisional and without serving as the basis for priority for any other application. Consequently, according to 35 U.S.C. 111(b)(5), Provisional A cannot be revived for any purpose, including to serve as a priority document for any other application.

To simplify analysis of the priority claim in the '994 publication, Applicants believe it is helpful to repeat the chronology of events:

Date	Event
March 20, 2000	Provisional A filed
February 23, 2001	Provisional B filed
March 21, 2001	Provisional A abandoned
July 9, 2001	Petition to convert Prov. B to a non-provisional (with priority claim to Prov. A)

One of the most basic tenets of domestic and foreign priority systems is that the benefit of an earlier application cannot be obtained if the one-year filing deadline is missed. For provisional applications, this rule is embodied in 35 U.S.C. § 111(b) (5)[1] which provides that a provisional application becomes abandoned when it is not converted to a non-provisional application within one year of filing.[2] This statute further states that once abandoned, the provisional application cannot be revived. Since Provisional A was not converted to a non-provisional application, Provisional A became abandoned on March 21, 2001 and is not subject to revival. 35 U.S.C. § 111(b) (5). Furthermore, as of March 20, 2001, no other application had been actually filed under 35 U.S.C. § 111(a) or via the PCT upon which to predicate domestic

---

[1]The full text of 35 U.S.C. § 111(b)(5) provides:

(5) Abandonment.--Notwithstanding the absence of a claim, upon timely request and as prescribed by the Director, a provisional application may be treated as an application filed under subsection (a). Subject to section 119(e)(3) of this title, *if no such request is made, the provisional application shall be regarded as abandoned 12 months after the filing date of such application and shall not be subject to revival after such 12-month period. (Emphasis added.)*

[2] Subject to the rule that conversion can be taken on the next available business day. Clearly not at issue here because March 20, 2001 fell on a Tuesday.

priority rights under 35 U.S.C. § 119(e)(1).[3] Accordingly, all domestic priority rights in Provisional A were extinguished as of March 21, 2001 (as were foreign priority rights[4]).

It is uncontroversial that a provisional application cannot claim priority to any other application. 35 U.S.C. § 111(b)(7). On March 21, 2001, when Provisional A expired, only Provisional B existed. Consequently, Provisional B was not entitled to the right of domestic or foreign priority of any other application or benefit of an earlier filing date of any other domestic (U.S.) application, including Provisional A.

With respect to the conversion of Provisional B to a non-provisional application, the conversion request of July 9, 2001 was timely filed within 5 months of Provisional B's filing date (February 23, 2001). Hence, Applicants do not dispute that Provisional B was properly converted to a non-provisional application—the '994 publication.

The question is whether '994 publication may properly claim domestic priority to Provisional A, which stood abandoned for more than 3 months on the date of Provisional B's conversion to the '994 publication. To be clear, this question is one of entitlement in the first instance and not simply a question of timing.[5]

First, Applicants believe that 35 U.S.C. § 111(b)(5) is clear and unambiguous on its face that 12 months after the filing date of any unconverted provisional application, that application shall be regarded as abandoned and shall not be subject to revival after such 12-month period.

---

[3] Applicants recognize that the provisional application need not be pending at the time such applications are filed provided that such applications were actually filed within 12 months of the provisional filing date. 37 C.F.R. § 1.78(a)(5). As discussed further herein, such applications do not include a non-provisional application that was converted from a provisional application. The requirements of 37 C.F.R. § 1.78(a)(5) address timing of the priority claim not whether a non-provisional application is entitled to make such a claim in the first instance.

[4] Under the Paris Convention, foreign priority rights are governed by Article 4, *see*, Art. 4.A.1 (existence of right) and 4.C.1 (period of priority for patents is 12 months).

[5] See footnote 3.

A provisional application that is not subject to revival cannot have any rights therein resurrected, including the right to serve as the basis of priority for another application which itself was filed more than 1 year after the filing date of the provisional. Applicants have found no case law or commentary to the contrary.

Second, 35 U.S.C. § 119(e)(1) provides domestic priority for an application for patent filed under 35 U.S.C. § 111(a) if that application was filed "not later than 12 months after the filing date on which the provisional application [for which it seeks priority] was filed."[6] However, the '994 publication is not an application for patent *actually* filed under 35 U.S.C. § 111(a). Rather, the '994 publication was filed as an application for patent under 35 U.S.C. § 111(b)(1) and converted to a non-provisional application pursuant to 35 U.S.C. § 111(b)(5). In this regard, it is instructive (and consistent) that 35 U.S.C. § 111(b)(5) only provides that the converted provisional *may* be treated as an application filed under 35 U.S.C. § 111(a), not that it *must* be so treated. Consequently, there is no absolute requirement that a non-provisional application converted from provisional application be treated in every respect as if actually filed under 35 U.S.C. § 111(a).

Third, the foregoing is further supported by 37 C.F.R. § 1.53(c)(3) which provides, and actually cautions, that a

> "provisional application . . . converted to a nonprovisional application . . . and accorded the original filing date of the provisional application . . . will result in the term of any patent to issue from the application being measured from at least the filing

---

[6] The relevant portion of 35 U.S.C. § 119(e)(1) provides:

(e)(1) An application for patent filed under section 111(a) or section 363 of this title for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in a provisional application filed under section 111(b) of this title, by an inventor or inventors named in the provisional application, shall have the same effect, as to such invention, as though filed on the date of the provisional application filed under section 111(b) of this title, if the application for patent filed under section 111(a) or section 363 of this title is filed not later than 12 months after the date on which the provisional application was filed and if it contains or is amended to contain a specific reference to the provisional application. . . .

> date of the provisional application . . . [and] applicants should consider avoiding this adverse patent term impact by filing a nonprovisional application claiming the benefit of the provisional application under 35 U.S.C. 119(e) (rather than converting the provisional application into a nonprovisional application pursuant to this paragraph)."[7]

This rule suggests conversion is undesirable and contemplates that the earliest date available for a converted non-provisional application is the filing date of the provisional application.

Fourth, the Paris Convention provides only for twelve months of foreign priority in patent cases (Paris Convention, Article 4.C.1), whereas the foregoing scenario could effectively provide two years of domestic priority to any U.S. application. Here is how that situation arises. Suppose that Provisional X is filed on February 1, 2000, Provisional Y is filed on February 1, 2001 and then Provisional Y is converted to a non-provisional application a year later on February 1, 2002. All these actions would have been timely and if that were the end of the story, the non-provisional application would only have an earliest effective filing date as of February 1, 2001 with the usual one year of domestic priority. However, if the non-provisional application includes a priority claim to Provisional X, then the non-provisional application now has an earliest effective filing date of February 1, 2000 thus providing two years of domestic priority! This scenario, if allowable, would constitute a major loophole for U.S. applications and does not

---

[7] The relevant portion of 37 C.F.R. § 1.53(c)(3) provides:

> (3) A provisional application filed under paragraph (c) of this section may be converted to a nonprovisional application filed under paragraph (b) of this section and accorded the original filing date of the provisional application. The conversion of a provisional application to a nonprovisional application will not result in either the refund of any fee properly paid in the provisional application or the application of any such fee to the filing fee, or any other fee, for the nonprovisional application. Conversion of a provisional application to a nonprovisional application under this paragraph will result in the term of any patent to issue from the application being measured from at least the filing date of the provisional application for which conversion is requested. Thus, applicants should consider avoiding this adverse patent term impact by filing a nonprovisional application claiming the benefit of the provisional application under 35 U.S.C. 119(e) (rather than converting the provisional application into a nonprovisional application pursuant to this paragraph).

appear to have been intended by the Paris Convention. If such a scenario does not in fact violate the Paris Convention, it certainly violates it in spirit.

In conclusion, Applicants urge that the '994 publication is only entitled to an earliest effective filing of February 23, 2001 and is not entitled to claim priority of any abandoned provisional application that was filed more than one year prior to the date of the request for conversion (with allowance for weekends and holidays). For the '994 publication, that means any provisional application filed on or before July 6, 2000[8] and subsequently abandoned cannot serve as the basis of a priority claim for the '994 publication. Since Provisional A was filed on March 20, 2000 and became abandoned on March 21, 2001, the '994 publication cannot claim priority thereto. Accordingly, the earliest effective filing date of the '994 publication is February 23, 2001.

Accordingly, the '994 publication is only entitled to an earliest effective filing of February 23, 2001. Since this date is after Applicants' earliest effective filing date of May 8, 2000, the '994 publication does not constitute a proper reference under 35 U.S.C. § 102(e)(1) and is not available as prior art against the present application. For this reason alone, this rejection under 35 U.S.C. § 102(e) should be withdrawn.

Submission of Declaration

To expedite prosecution, Applicants submit herewith a Declaration Under 37 C.F.R. § 1.131 (hereafter "Declaration") by the inventors of this application, Dr. John A. Hamilton and Dr. Gary Anderson, to antedate the '994 publication and thereby remove it as a reference against the present application. The Declaration establishes that the claimed subject matter was invented

[8] Because July 9, 2001 was a Monday, any provisional application filed on July 7 or 8, 2000 would have been considered pending on July 9, 2001.

and reduced to practice prior to March 20, 2000 (which date, according to the Examiner, is the critical date of the '994 publication[9]) in Australia, a WTO member country before January 1, 1996.

The presently claimed subject matter is directed to methods of treating inflammation by administering antibodies specific for GM-CSF, M-CSF or a combination of such antibodies and provides animal data establishing the efficacy of such treatments. The Declaration indicates that experimental work occurred prior to March 20, 2000 that demonstrate that antibodies specific to GM-CSF or M-CSF are capable of ameliorating the effects of inflammation in a mouse by inhibiting or antagonizing the effects of GM-CSF or M-CSF on cells of the monocyte/macrophage lineage. Declaration, ¶¶2, 4 and 7.

In particular, prior to March 20, 2000, the inventors had observed that mice with a knockout mutation in GM-CSF (GM-CSF $^{-/-}$) demonstrated a significantly reduced incidence of arthritis compared to wild-type mice (GM-CSF $^{+/+}$) or heterozygous mice (GM-CSF $^{-/+}$). This observation indicated that inhibiting GM-CSF could be a means of treating or preventing inflammation. Declaration, ¶5.

In experiments conducted prior to March 20, 2000, DBA\1 mice were injected with type II collagen (CII) in Freund's Complete Adjuvant (FCA) to induce arthritis followed by treatment with neutralizing monoclonal antibody 22E9 specific for GM-CSF or an isotype control. The clinical score was monitored daily to ascertain the level of inflammatory arthritis present within the two groups of animals and demonstrated that animals treated with the 22E9 monoclonal antibody specific for GM-CSF developed significantly lower levels of disease than those treated

[9] Applicants firmly believe that the '994 publication is not entitled to an effective filing date of March 20, 2000 and submission of the Declaration is not to be construed as an admission thereof. Rather this Declaration is provided to establish a date of invention prior to March 20, 2000.

with the isotype control. Declaration, ¶6. The observed reduction in inflammatory arthritis induced by the GM-CSF-specific antibodies means that the antibody is inhibiting or antagonizing the effects of GM-CSF on cells of the monocyte/macrophage lineage. Specification, p. 7, l. 3-7 and p. 25, l. 4-7; Fig. 1; and Declaration, ¶2.

Additionally, prior to March 20, 2000, the inventors observed that mice with an inactivating mutation for M-CSF demonstrated significantly reduced arthritis compared to wild-type mice. This observation indicated that inhibiting M-CSF could be a means of treating or preventing inflammation. Declaration, ¶8.

In additional experiments conducted prior to March 20, 2000, arthritis was induced in DBA/1 mice followed by treatment with monoclonal antibody 5AI specific for M-CSF or with an isotype control antibody, DX48. The clinical score was monitored daily to ascertain the level of inflammatory arthritis present within the two groups of animals and demonstrated that animals treated with the 5AI monoclonal antibody developed significantly lower levels of disease than those treated with the isotype control. Declaration, ¶9. The observed reduction in inflammatory arthritis induced by the M-CSF-specific antibodies means that the antibody is inhibiting or antagonizing the effects of M-CSF on cells of the monocyte/macrophage lineage. Specification, p. 7, l. 3-7 and p. 25, l. 4-7; Fig. 1; and Declaration, ¶7.

Accordingly, the Declaration presents data obtained before March 20, 2000 which establishes that antibodies specific for GM-CSF or M-CSF were capable of ameliorating the effects of inflammation in a subject by inhibiting or antagonizing the effects of GM-CSF or M-CSF on cells of the monocyte/macrophage lineage. Declaration, ¶10. As such the present invention was completed and reduced to practice prior to the earliest possible effective date of

the '994 publication. Hence, this reference is not properly available against the present application and this rejection under 35 U.S.C. § 102(e) should be withdrawn.

The 103(a) Rejection

Claims 29, 30 and 34 remain rejected under 35 U.S.C. § 103(a) as allegedly rendered obvious by the '994 publication in view of U.S. Patent No 5,444,153 to Goss *et al.* (the '153 patent) or U.S. Patent No. 5,662,609 to Slepian *et al.* (the '609 patent). Since the '994 publication is not a valid reference against the present application, either because it is only entitled to an effective date of February 23, 2001 or because Applicants have sworn behind this reference, as evidenced by the enclosed Declaration, this rejection had been rendered moot and withdrawal thereof is respectfully requested.

Conclusion

In view of the foregoing amendments and remarks, Applicants firmly believes that the examined subject matter is in condition for allowance, which action is earnestly solicited. If any issues remain outstanding after consideration of this Amendment, the Examiner is invited to contact the undersigned to expedite prosecution of this case.

Respectfully submitted,

Date: June 28, 2006

M. Lisa Wilson
Reg. No. 34,045

Duane Morris LLP
380 Lexington Ave.
New York, NY 10168
Tel.: (212) 692-1000
Fax: (212) 692-1020
Direct Line: (212) 691-1092
Email: lwilson@duanemorris.com